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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,529	10/16/2003	Homme W. Hellinga	1579-863	4003

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,529

Applicant(s)

HELLINGA ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3-14-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 3-14-2005 is acknowledged. The traversal is on the ground(s) that there is a lack of showing that examining the claims of Groups I to IV would constitute an undue burden. This is not found persuasive because the searches required for the various groups would not be coextensive in scope. This constitutes an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-22 are pending. Claims 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 1-15 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 3-14-2005 has been considered. An initialed copy is attached hereto.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,277,627. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims sets are drawn to biosensors comprising a glucose binding protein (GBP) and a reporter group wherein said reporter group is attached to the GBP and can constitute a fluorophore or a redox cofactor. Moreover, since the cited patented claims encompass all possible attachment positions within the GBP and the disclosure of the cited patent contemplates the same (see column 4-5), the specific positions recited in the instant claims are deemed to be obvious variations of the patented biosensors.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 7, 8 and 15 are rendered vague and indefinite by the use of the term “specific positions of said bPBP”. It is unclear which “specific positions” are meant to be encompassed by said term.

Claim 1 is rendered vague and indefinite by the recitation of the positions “10, 93, 149 and 183”. It is unclear what is meant by those recitations as no base sequence for the glucose binding protein is recited.

Claim 4 is rendered vague and indefinite by the use of the term “said ligand”. It is unclear what ligand is referring to since the claim precludes the normal binding partner of the wild-type bPBP.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Amiss et al. (US 2003/0134346)

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Amiss et al. disclose biosensors comprising glucose binding proteins (GBP) and reporter groups wherein said GBP includes at least one mutation and at least one reporter group (paragraph 0017). Amiss et al. further disclose that mutations of binding proteins include the addition or substitution of cysteine groups, non-naturally occurring amino acids and replacement of substantially non-reactive amino acids with reactive amino acids to provide for the covalent attachment of electrochemical or photoresponsive reporter groups (see paragraph 0025) and that a variety of reporter groups can be used such as fluorophores and redox cofactors (see paragraph 0032)). Amiss et al. also disclose that said reporter groups can be attached to the GBPs by any conventional means throughout the length of the protein including position 149 (see paragraph 0034). With regard to the specific ΔI_{std} or ΔR_{max} values recited in claims 11-14, it is deemed in the absence of evidence to the contrary, that since the biosensors disclosed by Hellinga et al. are and those of the instant invention are the same they would necessarily have the same biochemical properties.

Claims 1 and 3-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Amiss et al. (US Patent 6,855,556)

Amiss et al. disclose biosensors comprising glucose binding proteins (GBP) and reporter groups wherein said GBP includes at least one mutation and at least one reporter group (column 3, lines 44-50). Amiss et al. further disclose that mutations of binding proteins include the addition or substitution of cysteine groups, non-naturally occurring amino acids and replacement of substantially non-reactive amino acids with reactive amino acids to provide for the covalent

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attachment of electrochemical or photoresponsive reporter groups (see column 5, lines 1-7) and that a variety of reporter groups can be used such as fluorophores and redox cofactors (see column 6, lines 55-59). Amiss et al. also disclose that said reporter groups can be attached to the GBPs by any conventional means throughout the length of the protein including position 149 (see column 6 line 65 to column 7, line8). With regard to the to the specific ΔI_{std} or ΔR_{max} values recited in claims 11-14, it is deemed in the absence of evidence to the contrary, that since the biosensors disclosed by Hellinga et al. are and those of the instant invention are the same they would necessarily have the same biochemical properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellinga et al. (WO 99/34212 – IDS filed 3-14-2005).

Hellinga et al. disclose biosensors comprising glucose binding proteins (GBP) and reporter groups wherein said GBP include mutations that allow site-specific introduction of the environmentally sensitive reporter group (see abstract). Hellinga et al. further disclose that said reporter groups can be site-specifically introduced by total synthesis, semi-synthesis or gene fusion (see page 7, lines 18-19) and that a variety of reporter groups can be used a fluorophores and redox cofactors (see page 8 lines 3-7 and claims 4-5). Hellinga et al. also disclose that said reporter groups can be positioned in the binding pocket (ligand binding pocket) or distally from the binding pocket (see page 9, line 13 to page 10, line14). Moreover, Hellinga et al. disclose that the binding protein can be mutated either within the binding site or at allosteric sites (see page 10, lines 14-17).

The disclosure of Hellinga et al. differs from the instant invention in that they don't specifically exemplify any other bPBP other than GBP. Moreover, they do not explicitly disclose the specific ΔI_{std} or ΔR_{max} values recited in claims 11-14.

However, Hellinga et al. disclose that the strategy for introducing reporter groups into the exemplified GBP was successfully used with MBP and PBP. Consequently it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the methods set forth by Hellinga et al. in making GBP based biosensors to the making of biosensors comprising other periplasmic binding proteins. One would have had a reasonable expectation of success as Hellinga et al. disclose the ability to apply strategies to multiple periplasmic binding proteins.

With regard to the to the specific ΔI_{std} or ΔR_{max} values recited in claims 11-14, it is deemed in the absence of evidence to the contrary, that since the biosensors disclosed by Hellinga et al. are and those of the instant invention are the same they would necessarily have the same biochemical properties.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellinga et al. (U.S. Patent 6,277,627 – IDS filed 3-14-2005).

Hellinga et al. disclose biosensors comprising glucose binding proteins (GBP) and reporter groups wherein said GBP include mutations that allow site-specific introduction of the environmentally sensitive reporter group (see abstract). Hellinga et al. further disclose that said reporter groups can be site-specifically introduced by total synthesis, semi-synthesis or gene fusion (see column 1, lines 46-48) and that a variety of reporter groups can be used a fluorophores and redox cofactors (see column 3, lines 48-52 and claims 4-5). Hellinga et al. also disclose that said reporter groups can be positioned in the binding pocket (ligand binding pocket) or distally from the binding pocket (see column 4 lines 21-48). Moreover, Hellinga et al. disclose that the binding protein can be mutated either within the binding site or at allosteric sites (see column 4, lines 49-53).

The disclosure of Hellinga et al. differs from the instant invention in that they don't specifically exemplify any other bPBP other than GBP. Moreover, they do not explicitly disclose the specific ΔI_{std} or ΔR_{max} values recited in claims 11-14.

However, Hellinga et al. disclose that the strategy for introducing reporter groups into the exemplified GBP was successfully used with MBP and PBP. Consequently it would have been

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obvious to one of ordinary skill in the art at the time of the invention to apply the methods set forth by Hellinga et al. in making GBP based biosensors to the making of biosensors comprising other periplasmic binding proteins. One would have had a reasonable expectation of success as Hellinga et al. disclose the ability to apply strategies to multiple periplasmic binding proteins.

With regard to the to the specific ΔI_{std} or ΔR_{max} values recited in claims 11-14, it is deemed in the absence of evidence to the contrary, that since the biosensors disclosed by Hellinga et al. are and those of the instant invention are the same they would necessarily have the same biochemical properties.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

February 17, 2006